IN THE CLAIMS

This listing of claims will replace all prior versions and listing of claims in the application. The following amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

1. (Currently Amended) A method of improving sexual performance that excludes all of the known compounds that inhibit synthesis of sex hormone binding globulin that include but are not limited to methyltestosterone and fluoxymesterone, and all salts, esters, amides, enantiomers, isomers, tautomers, prodrugs and derivatives of these compounds, comprising:

(a) administering a pharmaceutical composition to skin of the subject, the composition comprising, a pharmacologically effective amount of testosterone, a penetration enhancer, a C1-C4 alcohol, and a gelling agent forming a hydroalcoholic gel formulation.

(b) administering a pharmacologically effective amount of a phosphodiesterase inhibitor to the subject after the administration of the gel formulation

2. (Original) The method of claim 1, wherein the penetration enhancer comprises at least one of a C8-C22 fatty acid.

3. (Original) The method of claim 2, wherein the fatty acid comprises an alkyl chain length of at least 12 carbon atoms.

4. (Original) The method of claim 1, wherein the alcohol comprises at least one of ethanol, 2-propanol, n-propanol, or mixtures thereof.

5. (Original) The method of claim 1, wherein the inhibitor is administered in a single dose.

6. (Original) The method of claim 1, wherein the hydroalcoholic gel formulation is administered in a single dose or divided dose.

7. (Original) The method of claim 1, wherein the inhibitor is administered within about 24 hours after the administration of the hydroalcoholic gel formulation.

8. (Original) The method of claim 1, wherein the inhibitor is selected from the group consisting of a type III phosphodiesterase inhibitor, a type N phosphodiesterase inhibitor, and a type V phosphodiesterase inhibitor.

9. (Original) The method of claim 5, wherein the inhibitor is a type V phosphodiesterase inhibitor selected from the group consisting of sildenafil, sildenafil citrate,zaprinast,MY5445, dipyridamole, and vardenafil, or an enantiomer, isomer, or salt thereof.

10. (Original) The method of claim 1, wherein the inhibitor is sildenafil citrate administered in an amount of about 25 mg to about 200 mg.

11. (Original) The method of claim 1, wherein the inhibitor is sildenafil citrate administered in an amount of about 25 mg, 50mg, or 100mg..

12. (Original) The method of claim 1, wherein the inhibitor is administered via a route selected from the group consisting of oral, intranasal, inhalation, parenteral and percutaneous.

13. (Original) The method of claim 10, wherein the sildenafil citrate is administered orally in an amount of about 25 mg, 50 mg, or 100 mg.

14. (Original) The method of claim 12, wherein the sildenafil citrate is administered intranasally in an amount of about 10 mg, 20 mg, or 40 mg.

15. (Original) The method of claim 1, wherein the subject achieves hormonal steady state levels of testosterone.

16. (Original) The method of claim 1, wherein the subject is hypogonadal.

17. (Original) The method of claim 1, wherein the enhancer is isopropyl myristate.

18. (Original) The method of claim 17, wherein the isopropyl myristate is present in a concentration selected from the group consisting of about 0.5%, 1%, 2%, 3%, 4%, and 5% weight to weight of the composition.

19. (Original) The method of claim 18, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the composition.

20. (Original) The method of claim 1, wherein the gelling agent is selected from the group consisting of polyacrylic acid, and carboxymethylcellulose.

21. (Original) The method of claim 1, wherein the gelling agent is polyacrylic acid present in a concentration of about 1% weight to weight of the composition.

22. (Original) The method of claim 1, wherein the alcohol is present in a concentration of about 72.5% weight to weight of the composition.

23. (Original) The method of claim 1, wherein the testosterone is present in a concentration selected from the group consisting of about 0.5%, 1%, 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, and 10% weight to weight of the composition.

24. (Original) The method of claim 1, wherein the pharmaceutical composition further comprises sodium hydroxide.

25. (Currently amended) The method of claim 1, wherein the pharmaceutical composition comprises:

(a) about 0.5% to about 10% testosterone;

(b) about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;

(c) about 0.1% to about 5% isopropyl myristate;

(d) about 1% to about 5% 0.1 N sodium hydroxide solution; and

(e) about 0.1% to about 5% of a gelling agent;

wherein the percentages of the components are weight of the composition.

26. (Original) The method of claim 1, wherein the composition is contained in a packet selected from the group consisting of a unit dose packet and a multiple dose packet.

27. (Currently amended) A method of improving sexual performance, comprising:

(a) administering a pharmaceutical composition to skin of the subject, the composition comprising, a pharmacologically effective amount of testosterone, a penetration enhancer, a C1-C4 alcohol, and a gelling agent forming a hydroalcoholic gel formulation.

(b) administering a pharmacologically effective amount of a phosphodiesterase inhibitor as the sole additional pharmaceutical to address the sexual performance of ~~to~~ the subject after the administration of the gel formulation.

28. (Original) The method of claim 27, wherein the penetration enhancer comprises at least one of a C8-C22 fatty acid.

29. (Original) The method of claim 28, wherein the fatty acid comprises an alkyl chain length of at least 12 carbon atoms.

30. (Original) The method of claim 27, wherein the alcohol comprises at least one of ethanol, 2-propanol, or n-propanol, and mixtures thereof.

31. (Original) The method of claim 27, wherein the pharmaceutical agent for treating erectile dysfunction is administered in a single dose.

32. (Original) The method of claim 27, wherein the hydroalcoholic gel formulation is administered in a single dose or divided dose.

33. (Original) The method of claim 27, wherein the pharmaceutical agent for treating erectile dysfunction is administered within about 24 hours after the administration of the hydroalcoholic gel formulation.

34. (Original) The method of claim 27, wherein the pharmaceutical agent for treating erectile dysfunction is selected from the group consisting of pentoxifylline, yohimbine, apomorphine, alprostadil, papavaerine, and phentolamine, or a combination, salt, derivative or enantiomer thereof.

35. (Original) The method of claim 34, wherein the pharmaceutical agent for treating erectile dysfunction is apomorphine administered orally in an amount of about 2 mg to about 3 mg.

36. (Original) The method of claim 27, wherein the pharmaceutical agent for treating erectile dysfunction is administered via a route selected from the group consisting of oral, intranasal, inhalation, parenteral, and percutaneous.

37. (Original) The method of claim 27, wherein the subject achieves hormonal steady state levels of testosterone.

38. (Original) The method of claim 27, wherein the subject is hypogonadal.

39. (Original) The method of claim 27, wherein the enhancer is isopropyl myristate.

40. (Original) The method of claim 39, wherein the isopropyl myristate is present in a concentration selected from the group consisting of about 0.5%, 1%, 2%, 3%, 4%, and 5% weight to weight of the composition.

41. (Original) The method of claim 40, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the composition.

42. (Original) The method of claim 27, wherein the gelling agent is selected from the group consisting of polyacrylic acid, and carboxymethylcellulose.

43. (Original) The method of claim 27, wherein the gelling agent is polyacrylic acid present in a concentration of about 1% weight to weight of the composition.

44. (Original) The method of claim 27, wherein the alcohol is present in a concentration of about 72.5% weight to weight of the composition.

45. (Original) The method of claim 27, wherein the testosterone is present in a concentration selected from the group consisting of about 0.5%, 1%, 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, and 10% weight to weight of the composition.

46. (Original) The method of claim 27, wherein the pharmaceutical composition further comprises sodium hydroxide.

47. (Currently amended) The method of claim 27, wherein the pharmaceutical composition comprises:

(a) about 0.5% to about 10% testosterone;

(b) about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;

(c) about 0.1% to about 5% isopropyl myristate;

(d) about 1% to about 5% 0.1 N sodium hydroxide solution; and

(e) about 0.1% to about 5% of a gelling agent;

wherein the percentages of components are weight to weight of the composition.

48. (Original) The method of claim 27, wherein the composition is contained in a packet selected from the group consisting of a unit dose packet, and a multiple dose packet.

49. (New) The method of claim 27, wherein the inhibitor is selected from the group consisting of a type III phosphodiesterase inhibitor, a type N phosphodiesterase inhibitor, and a type V phosphodiesterase inhibitor.

50. (New) The method of claim 49, wherein the inhibitor is a type V phosphodiesterase inhibitor selected from the group consisting of sildenafil, sildenafil citrate, zaprinast, MY5445, dipyridamole, and vardenafil, or an enantiomer, isomer, or salt thereof.

51. (New) The method of claim 27, wherein the inhibitor is sildenafil citrate administered in an amount of about 25 mg to about 200 mg.